



October 2, 2024

**BSE Limited**

P J Towers,  
Dalal Street,  
Mumbai-400001

**Code: 532321**

**National Stock Exchange of India Limited**

Exchange Plaza,  
C/1, Block G,  
Bandra-Kurla Complex, Bandra (East),  
Mumbai-400051

**Code: Zyduslife**

**Re.:** Press Release

Dear Sir / Madam,

Please find enclosed a copy of press release dated October 2, 2024, titled "**Zydus receives tentative approval from USFDA for Enzalutamide Tablets, 40 mg and 80 mg**".

The contents of the press release give full details.

Please bring the aforesaid news to the notice of the members of the exchange and the investors at large.

Thanking you,

Yours faithfully,  
For, **ZYDUS LIFESCIENCES LIMITED**

**DHAVAL N. SONI**  
**COMPANY SECRETARY**

**Encl.:** As above

**Zydus Lifesciences Limited**

Regd. Office : 'Zydus Corporate Park', Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle,  
S. G. Highway, Ahmedabad-382 481, Gujarat, India. | Phone : +91-79-71800000, +91-79-48040000  
website : www.zyduslife.com | CIN : L24230GJ1995PLC025878



## **Zydus receives tentative approval from USFDA for Enzalutamide Tablets, 40 mg and 80 mg**

*Ahmedabad, India, 02 October, 2024*

Zydus Lifesciences Limited (including its subsidiaries/ affiliates, hereafter referred to as “Zydus”) has received tentative approval from the United States Food and Drug Administration (USFDA) to manufacture Enzalutamide Tablets, 40 mg and 80 mg (USRLD: Xtandi® Tablets, 40 mg, 80 mg).

Enzalutamide tablets are androgen receptor inhibitors indicated for the treatment of patients with castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. Enzalutamide Tablets will be produced at the Group’s manufacturing site at SEZ, Ahmedabad.

Enzalutamide tablets, 40 mg and 80 mg had annual sales of USD 1417.2 mn in the United States (IQVIA MAT July 2024).

The group now has 400 approvals and has so far filed over 465\* ANDAs since the commencement of the filing process in FY 2003-04.

*(\*as of 30th June 2024)*



**PRESS  
RELEASE**

For further information please contact :  
**The Corporate Communications Department**

**Zydus Lifesciences Limited**

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